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10/532,727	04/27/2005	Yoshikazu Ogura	271496US0PCT	8749
22850 7590 10/02/2008 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER WEIER, ANTHONY J	
			ART UNIT	PAPER NUMBER
			1794	
			NOTIFICATION DATE	DELIVERY MODE
			10/02/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/532,727	Applicant(s) OGURA ET AL.	
	Examiner Anthony Weier	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 11-14, 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :4/27/05, 1/9/06, 2/9/06, 6/12/06, 12/14/07.

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-10 and 15-19) in the reply filed on 7/18/08 is acknowledged. The traversal is on the grounds that the Examiner has not provided any indication that the contents of the claims were considered in making the assertion of lack of unity and that lack of unity would not be appropriate between a product and a process especially adapted for manufacture of said product. This is not found persuasive because the contents of the claims were considered in making the assertion of a lack of unity. In particular, the process claims are not seen as specifically being adapted for the claimed process. The product requires the presence of caffeine while the process pertains to removal of caffeine (and, therefore, would provide a differing product from the product as presently claimed). Such difference in claimed subject matter would require different searches (not completely commensurate with one another) as well as differing search strategies.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112, 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 10 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Limitations critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re*

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Mayhew, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). In particular, the instant claims call for the removal of caffeine from a caffeine-containing catechin composition using contact with solvent, water, activated carbon and/or clay, and distillation of said solvent. However, the instant claims do not direct one as to how or if the caffeine is actually separated from the mixture. The original specification discloses removal of, for example, the activated carbon or clay and accompanying precipitates by filtration (see Example 1).

Claim Rejections - 35 USC § 112, 2nd Paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 and 10 are confusing in that same call for selective removal of caffeine from a caffeine containing catechin composition yet do not actually present a step that separates same. In other words, the claims appear to end the process with either the contact of the solvent treated catechin composition with activated carbon and/or clay or adding water and subsequently distilling the solvent from the caffeine containing catechin composition. Without removal of any precipitates formed or the activated carbon/clay, it would appear that the composition continues to possess caffeine.

In claims 1-4, it is not clear as to what the ratio range of 9/1 to 1/9 is based on.

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The solvent to water? The catechin composition to solvent solution?

Claims 7-9 are indefinite with respect to the independent claims same depend from in so much as it is not clear when the addition of water and distilling off of solvent is to occur in relation to the activated carbon and clay treatment steps. Also, in claims 7-9, it is not clear as to what the range of ratios "10/0 to 8/2" is based on. Is this the ratio for organic solvent to water? If so, then the endpoint "'10/0" contradicts the use of **both** organic solvent and water and not said solvent alone.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-10 and 15-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-19 and 22-25 of copending Application No. 10/581200. Although the conflicting claims are not

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identical, they are not patentably distinct from each other because, for example, same vary slightly in the amount of caffeine containing catechin composition (e.g. green tea extract) per mixed solution or mixture as well as a difference in range (though overlapping) of the amount of non-polymer catechins contained in said composition. However, such differences are not seen as providing a patentable distinction, and it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the ratios of 10/581200 slightly as a matter of preference depending on, for example, the amount of each component readily available. In addition, the instant claims further recite steps of removing impurities (undissolved solids) and the solvent used. However, it would have been obvious to have included such step in the process claims of 10/581200 since providing same would provide better isolation of or purification of the catechin composition for subsequent consumer use. Otherwise, the instant claims essentially are generic to those of copending Application no. 10/581200. In particular, the claims of 10/581200 recite a process of removing caffeine using a particular ratio of green tea extract containing caffeine with a mixture of organic solvent, water, activated carbon and acid clay or activated clay. The instant claims are generic to same as they provide for treatment of any caffeine containing catechin source.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

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6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3, 5, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 6-128168.

JP 6-128168 discloses a process wherein a caffeine-containing catechin composition (e.g. tea) is treated in a mixture of water and organic acids (e.g. ethanol) in a ratio within the range as set forth in the instant claims (e.g. 100 g tea/ 300 g solution) wherein same is then treated with activated charcoal (i.e. activated carbon) or acid clay, same inherently selectively removing caffeine. See Abstract.

Due to the similarity in processing, it is considered inherent that the extract attained would have a non-polymer catechin to caffeine ratio as called for in instant claim 10.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 3, 5-9, and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 46-39058.

JP 46-39058 discloses a process wherein a caffeine-containing catechin

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composition (e.g. tea) is treated in a mixture of water and organic acids (e.g. ethanol) wherein same is then treated with activated charcoal (i.e. activated carbon) same inherently selectively removing caffeine. JP 46-39058 further discloses the steps of distilling of the solvent as well as further purifying the treated composition (inherently including removal of undissolved solids). See Abstract.

Due to the similarity in processing, it is considered inherent that the extract attained would have a non-polymer catechin to caffeine ratio as called for in instant claim 10 and the particular product limitations as set forth in claim 18.

The claims further call for the particular percentage of caffeine-containing catechin composition in said solution or the percentage of organic solvent to water (see rejection under 35 USC 112, 2nd paragraph above). However, such determination in either case would have been well within the purview of a skilled artisan, and it would have been obvious to one having ordinary skill in the art at the time of the invention to have arrived at such amount through routine experimental optimization.

The claims further call for the non-polymer catechin content of the caffeine-containing catechin composition. Absent a showing of unexpected results, the determination of the most effective particular solids content and/or catechin content of the tea source would have been further obvious through routine experimental optimization.

10. Claims 2 and 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 46-39058 taken together with JP 6-128168.

The claims further call for the use of acid clay in combination with activated

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carbon. As both are known for removal of impurities from tea extracts, it would have been obvious to one having ordinary skill in the art at the time of the invention to have employed both singly or in combination to provide the same benefit. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. *in re Kerkhoven*, 205 USPQ 1069.

11. Claims 1-6, 10, and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 6-128168.

The claims further call for the use of acid clay in combination with activated carbon. As both are known for removal of impurities from tea extracts, it would have been obvious to one having ordinary skill in the art at the time of the invention to have employed both singly or in combination to provide the same benefit. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. *in re Kerkhoven*, 205 USPQ 1069.

Due to the similarity in processing, it is considered inherent that the extract attained would have the particular product limitations as set forth in claim 18.

The claims further call for the non-polymer catechin content of the caffeine-containing catechin composition. Absent a showing of unexpected results, the determination of the most effective particular solids content and/or catechin content of the tea source would have been further obvious through routine experimental optimization.

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If it is shown that the ratio range set forth in claims 1-4 involve the ratio of organic solvent to water, the following should be noted (see rejection under 35 USC 112, 2nd paragraph above). Such determination would have been well within the purview of a skilled artisan, and it would have been obvious to one having ordinary skill in the art at the time of the invention to have arrived at such amount through routine experimental optimization.

Prior Art

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony Weier whose telephone number is 571-272-1409. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Anthony Weier
September 25, 2008